REMARKS

In the first Official Action issued in this application, to which the present Response is addressed, claims 1-10, 14-26, 30-46 and 48-62 were all rejected under 35 U.S.C. §102(a) as anticipated by Lewis et al., U.S. Patent No. 5,902,235. The remainder of the claims were all rejected as unpatentable over Lewis '235 in view of Chance, U.S. Patent No. 5,853,370. All of the claims presented in this application are amended to more clearly set forth the underlying invention, with the exception of claims 8, 13, 14, 15, 16, 34, 36-39 inclusive, which are cancelled herewith, without prejudice.

Applicant wishes to point out, at the outset, that the cited Lewis '235 patent is commonly owned with the present application, and Applicant is very aware of the content of the Lewis patent as well as with its underlying technology. In this regard, Applicant points out that the present invention represents a significant extension of the basic technology set forth in Lewis '235, and submits that the concurrent monitoring and simultaneous substantially instantaneous display of data from different regions of the same test subject according to the present invention is entirely unapparent from the Lewis '235 patent, based on the actual experience of the inventors involved, and was entirely unforeseen at the time subject matter of the Lewis '235 patent was invented, or at the time that patent was issued or at the time the present invention was made. The present invention is an extension of the technology disclosed in the Lewis '235 patent, based upon the entirely unforeseen value in comparatively and concurrently determining and displaying the different states of blood metabolite present (e.g., hemoglobin oxygen saturation), present in each of the two different brain hemispheres of humans and other such test subjects.

In this foregoing regard, it is noted that in characterizing the prior art as a foundation for the stated rejections the Examiner refers to "spanning" the two different brain hemispheres, but that is precisely the opposite of what the invention does, and is contrary to the subject matter claimed. The claimed invention teaches one to examine each brain hemisphere or other such separate area separately and entirely apart from the other such area, but to display the two separate quantitative results adjacent one another for direct concurrent review.

In essence, both Lewis '235 and all prior such teachings appear to be oblivious of and fail to even mention the existence of the two separate brain hemispheres and of their potentially different states of oxygenation. Therefore, it is completely unfounded to say that there is even any implied or inherent teaching of the invention disclosed and claimed in the present subject matter in Lewis '235, or in the Chance 5,853,370 patent of record herein, or indeed, in any of the prior patents including the references cited of record herein. In this regard, as was well stated in the case of *In re Rijchaert*, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993)

> "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112; *In re Rijchaert*, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993). "In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. and Inter. 1990) (emphasis original).

All of the claims as now presented clearly set forth this concept of directly comparative concurrent spectrophotometric in vivo monitoring and display of selected blood metabolites present in a plurality of different internal regions of the same test subject on a continuing basis. The most that can possibly be said for the prior art is that it basically shows that different areas of the human brain or other such test subject may be analyzed from either a single or from multiple different sensor locations. It does not, however, teach the concurrent monitoring and comparative display of the same blood metabolite from two different areas of the same test subject, and particularly do not teach this concept with respect to the two different brain hemispheres of a human being or like subject.

Accordingly, it is submitted that the claims as now presented clearly and definitely distinguish over references such as Lewis '235 or, for that matter, the applied reference of Chance, 5,853,370; indeed, it is submitted that even a cursory review of either of these two patents clearly shows that they simply contemplate the possibility of taking in vivo spectrophotometric samplings from a plurality of differing regions in a given test subject, but they do not contemplate the invention as claimed, in which two different areas having differing

boundaries and constituting different organic segments of the same test subject are concurrently monitored, analyzed, and comparatively displayed for direct, immediate examination by an attending physician or the like. This concept is highly novel and significant, and it has escaped the attention of prior inventors for many years heretofore.

In the foregoing regard, it is pointed out that the invention disclosed in the Lewis '235 patent is not properly combinable with that disclosed in the Chance '370 patent with respect to the present invention or for the reasons set forth by the Examiner in stating the rejections of records since Lewis is devoted to the concept of sampling and analyzing data for the purpose of obtaining quantitative individual data readings, but Chance is devoted to the totally different concept of "a defined spatial image of the tissue by effectively producing from signals from a multiplicity of photon migration paths in the tissue a succession of data sets representing, from a selected view, a succession of spatial images of the tissue being stimulated and the tissue not being stimulated, and an image data set related to the difference between data of the successive data sets of the stimulated and non-stimulated tissue." Thus, Chance is in fact directed to a totally different technology (i.e., imaging), even though in a broad sense it involves spectrophotometric technologies and analytical processing, producing entirely different kinds of data that that contemplated and sought by the Lewis '235 disclosure. In point of fact, apart from the very basic fact that spectrophotometry is involved, the inventions of Lewis and Chance are entirely separate and distinct from one another.

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As indicated above, it is believed that the claims as now presented do particularly set out Applicant's invention in relation to the applied art, and clearly distinguish over the art. Consequently, it is believed that all of the claims as now presented are clearly allowable over the art, and a Notice in accordance therewith is believed in order and respectfully solicited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 1, 2, 9, 11, 17-19, 27-33, 35, 40, 42, 48, 49, and 59 have been amended as follows.

1. (Amended) A method for comparative spectrophotometric in vivo monitoring and display of selected blood metabolites present in a plurality of different internal regions of the same test subject on a continuing and substantially [simultaneous] concurrent basis, comprising the steps of:

applying a [plurality of] separate spectrophotometric sensor[s] to a test subject at each of a [corresponding] plurality of separate testing sites and coupling each such sensor to a control and processing station;

operating a selected number of said sensors on a substantially concurrent basis to spectrophotometrically irradiate at least two separate internal regions of the test subject during a common time interval, each such region being associated with a different such testing site;

separately detecting and receiving the light energy resulting from said spectrophotometric irradiation for each of said at least two different regions, and conveying separate sets of signals to said control and processing station which correspond to the separately detected light energy from said at least two different regions;

separately and concurrently analyzing said conveyed signals to separately determine quantified data representative of and evaluating the same selected blood metabolite in each of said at least two internal regions; and

concurrently visually displaying said separately determined quantified data for each of said at least two different regions for direct concurrent mutual comparison.

2. (Amended) The method of claim 1, wherein said step of analyzing comprises quantitative determination of blood oxygenation level within each of said at least two regions.

9. (Amended) The method of claim 1, wherein said sensors are applied to the head of the test subject and used to monitor mutually separate regions within the brain.

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11. (Amended) The method of claim 9, wherein said sensors are positioned in locations proximate to different brain hemispheres and said two mutually separate internal regions are each located in a different such brain hemisphere.

17. (Amended) Apparatus for concurrent comparative spectrophotometric in vivo monitoring of selected blood metabolites present in each of a plurality of different internal regions on a continuing [substantially concurrent] basis, comprising:

a plurality of spectrophotometric sensors, each attachable to a test subject at a different test location and adapted to separately but concurrently spectrophotometrically irradiate a [given] different region within the test subject associated with each such test location;

a controller and processor, and circuitry coupling each such sensor to said controller and processor for separately and individually but concurrently operating certain of said sensors to spectrophotometrically irradiate each of said [given] different internal region within the test subject associated with each such test location;

said sensors each further adapted to receive light energy resulting from the separate spectrophotometric irradiation by that sensor of its associated different region on a substantially concurrent basis with other such sensors, and to produce separate signals corresponding to the light energy so received; and said circuitry acting to convey said separate signals to said controller and processor for separate analytic processing;

said controller and processor adapted to analytically process said conveyed signals separately and thereby determine separate quantified blood metabolite data therefrom for separate such sensors and different associated regions; and

a visual display coupled to said controller and processor and adapted to separately but concurrently display the quantified metabolite data so determined for each of a plurality of sensors in a mutually-comparative manner.

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18. (Amended) The apparatus of claim 17, wherein said controller and processor is adapted to analyze said data to quantitatively determine blood oxygenation within at least two separate internal regions.

19. (Amended) The apparatus of claim 18, wherein said controller and processor is adapted to produce separate numeric value designations for hemoglobin oxygen saturation for at least two of said different regions.

27. (Amended) The apparatus of claim 25, wherein at least two of said sensors are adapted to be positioned in locations associated with mutually different hemispheres of the same brain and [are] each such sensor is operable to separately monitor at least portions of each such different hemisphere.

28. (Amended) The apparatus of claim 27, wherein said controller and processor is adapted to determine cerebral blood oxygenation saturation within each of said two different brain hemispheres.

29. (Amended) The apparatus of claim 27, wherein said sensors are adapted to provide signals to said controller and processor which comprise at least two data sets that cooperatively define at least portions of a particular area within the same [such internal regions] hemisphere of said brain.

30. (Amended) The apparatus of claim 24, wherein said data sets provided by said sensors include one such set characterizing a first [zone adjacent] part of said [given region] particular hemisphere area and another such set characterizing a second [zone at least partially within said given region] part of said particular hemisphere area.

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31. (Amended) The apparatus of claim 30, wherein said second [zone] part of said particular hemisphere area characterized by said other such data set includes at least part of said first [zone] part of said hemisphere area.

33. (Amended) A method for [substantially simultaneous] concurrent comparative in vivo monitoring of blood metabolites in each of a plurality of different internal regions [of at least one] in a selected test subject, comprising the steps of:

spectrophotometrically irradiating each of a plurality of different testing sites on said [at least one] test subject;

detecting light energy resulting from said spectrophotometric irradiation for a plurality of such testing sites, and providing separate sets of signals to a control and processing station which are representative of the light energy so received for each of said plurality of testing sites and which cooperatively define blood metabolite data for an individual one of said defined regions;

analyzing said conveyed signals to determine quantified blood metabolite data representative of at least one defined region within said at least one test subject associated with each of at least two different such testing sites, each such defined region being different from the other; and

concurrently displaying said data for each of said at least two different regions at substantially the same time for direct mutual comparison.

35. (Amended) The method of claim [34] 33, wherein said provided data sets include one such set which characterizes a first zone [proximate to] within said defined region and another such set which characterizes a second zone that is at least partially within said defined region.

40. (Amended) The method of claim 33, wherein said spectrophotometric irradiation comprises application of at least two different wavelengths[,] and such wavelengths are applied in an alternating sequence of timed pulses, detection of the resulting light energy corresponding to each of said wavelengths is done on a timed periodic basis using periods whose occurrence generally corresponds to that of said applied spectrophotometric wavelength pulses.

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42. (Amended) The method of claim [41] 40, wherein the duration of each of said timed detection periods is limited to a length which is less than that of each pulse of applied spectrophotometric irradiation energy.

48. (Amended) Apparatus for spectrophotometric in vivo monitoring of a selected metabolic condition in each of a plurality of different test subject regions on a substantially concurrent basis, comprising:

a plurality of spectrophotometric emitters, each adapted to separately spectrophotometrically irradiate a designated region within a test subject from a test location on such test subject;

a controller and processor, and circuitry coupling each such emitter to said controller and processor for individually operating selected such emitters to spectrophotometrically irradiate at least two particular regions within a test subject from at least one selected test location;

a plurality of detectors, each adapted to separately receive light energy resulting from the spectrophotometric irradiation of said at least two particular regions, and to produce at least one separate set of corresponding signals for each such region; and circuitry acting to convey said separate sets of signals to said controller and processor for analytic processing;

said controller and processor adapted to analytically process said conveyed sets of signals to determine separate sets of quantified data representative of said metabolic condition in said at least two regions; and

a visual display coupled to said controller and processor and adapted to display separate representations of said separate sets of quantified metabolic data for each of said at least two regions in a mutually-comparative manner and on a substantially [simultaneous] concurrent basis.

49. (Amended) The apparatus of claim 48, wherein said controller and processor includes a computer programmed to analyze said detector signals to separately determine the blood oxygenation state within each of said at least two regions.

59. (Amended) The apparatus of claim 57, wherein at least certain of said operational emitter and detector pairs include at least two detectors, and wherein at least one [such] detector of such a pair is located nearer the emitter of such pair than at least one of the other detectors to thereby provide near and far detector groupings for that operational pair of emitter and detectors.